

### REMARKS

Claims 55, 57-61, 63-66, 68-69, and 71-81 constitute the pending claims in the present application. Applicants cancel, without prejudice, claim 58. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note with appreciation that the reply filed February 6, 2003 has been entered in full. Applicants additionally note that any rejection of record that is not addressed in this action has been withdrawn.
2. Applicants note with appreciation that the Information Disclosure Statement filed October 1, 2002 has been considered by the Examiner.
3. Applicants submit herewith corrected drawings which are believed to obviate the objection.
4. Claims 55, 57-61, 63-66, 68, 69 and 71-81 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

As outlined in detail in MPEP 2163, “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” (See, for example, *Vas-Cath, Inc. v Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991)). “[T]he ‘essential goal’ of the description of the invention requirement is to clearly convey the information that an application has invented, the subject matter of which is claimed.” (*In re Barker*, 559 F.2d 588, 592 n.4 194 USPQ 470, 473 n.4 (CCPA 1977)).

Applicants contend that the specification provides extensive support for the claimed subject matter, and accordingly satisfies the requirements of 35 U.S.C. 112, first paragraph. Applicants direct the Examiner’s attention to the following portions of the specification in which

Applicants provide one of skill in the art extensive guidance as to the exemplary agents for use in the methods of the present invention: page 6, lines 19-35; page 7, lines 1-12; page 20, lines 1-34; page 25, lines 3-35; page 26, lines 1-29; Examples 1-2; and Examples 6-7. Applicants' description of exemplary agents for use in the claimed methods includes not only the names of these known agents, but also a discussion of their structural and functional properties. Furthermore, Applicants point out that the growth factors, cAMP elevating agents, and steroids discussed in detail in the specification are also known in the art. Accordingly, one of skill in the art also has at their disposal, the extensive knowledge in the art concerning the structure of each of the growth factors, cAMP elevating agents, and steroids reviewed in the specification. Applicants contend that the specification satisfies the written description requirement "by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." (*Lockwood v American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)).

The Examiner has cited the Federal Circuit's finding in *The Regents of the University of California v. Eli Lilly and Co.* to support the Examiner's allegation that Applicants' have failed to adequately describe the claimed subject matter. Applicants contend, however, that the finding in *Lilly* supports Applicants' position, and that the Examiner is misinterpreting the *Lilly* decision and using it to impose what amounts to a Super Enablement rejection.

In *Lilly*, the Federal Circuit addressed the question of how to adequately describe a genus of materials. In outlining that which constitutes an adequate description of a genus with respect to genetic material, the court asserted that adequate description requires more than the gene or protein name.

"[A] cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA. See *Fiers*, 984 F.2d at 1171, 25 U.S.P.Q.2D (BNA) at 1606. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus **or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.**" (emphasis supplied) 119 F.3d at 1566

Accordingly, for the description of a genetic invention to be deemed adequate to describe the genus that the claims encompass requires either a recitation of the structure (i.e., sequence) of a representative number of members of the genus **or** a recitation of the common features of the members of the claimed genus. Applicants contend that the description provided in the application satisfies the standards outlined in *Lilly*, and that the Examiner's use of *Lilly* to support this rejection is due to either a misinterpretation of *Lilly* or to a failure to recognize the differences between the fact patterns in the two applications. In the present application, the specification provides an extensive list of exemplary agents for use in the subject methods. Although the application does not supply the particular sequence or structure of all of these agents, each is well known in the art. Accordingly, the mere utterance of the term fibroblast growth factor or dexamethasone immediately allows one of skill in the art to envision the agents for use in the subject methods.

"In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." 119 F.3d at 1566

Applicants submit that the pending claims define the claimed subject matter in terms of generic formulae that indicate with specificity what the generic claims encompass, and accordingly meet the guidelines set forth above and comply with the written description requirement. The specification describes the claimed subject matter with reference to both structural and functional information, and Applicants' description based on both criteria stands in sharp contrast to the way in which the subject matter was described and claimed in *Lilly*. Accordingly, Applicants submit that based on both the Guidelines for the Examination of Patent

Applications, and based on the recent holdings of the Federal Circuit, Applicants have satisfied the requirements under 35 U.S.C. 112, first paragraph.

In summary, Applicants contend that the specification provides ample support to clearly indicate that Applicants, at the time of filing, had possession of the claimed invention. Applicants have provided extensive description of representative members of the genus of agents used in the subject methods, and accordingly Applicants have provided sufficient disclosure to allow one of skill in the art to readily envision that which is claimed. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out certain embodiments of Applicants' invention. Applicants' amendments are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

5. Claims 55, 57-61, 63-66, 68, 69 and 71-81 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the relevant art to practice the claimed invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

As outlined in detail in MPEP 2164, the enablement requirement of 35 U.S.C. 112, first paragraph, ensures "that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention." In the prior Office Action, the Examiner alleges that Applicants have failed to enable one of skill in the art to practice the presently claimed invention throughout its scope, and recites the Wands factors as supporting this allegation. We note however, that the Examiner has failed to cite any references which undermine the enablement of the presently claimed invention. Furthermore, the Examiner has failed to make of record any references to support his characterization of the invention and the state of the art, as discussed in reference to the Wands factors on pages 6-10 of the prior office action. Accordingly, Applicants respectfully submit that the Examiner has failed to make a prima facie case of lack of enablement of the presently claimed subject matter.

However, Applicants arguments in response to this rejection are not based on the Examiner's failure to make a prima facie case of lack of enablement alone. Applicants

additionally disagree with the characterization of the presently claimed invention, and the characterization of the teachings of the specification. First, as a policy matter, Applicants contend that the reasoning underlying the Examiner's rejection amounts to a desire to impose upon Applicants an unduly high standard of enablement. The Examiner's arguments suggest a belief that Applicants are entitled to claims no broader than the specific working examples provided in the specification. This is clearly contrary to the purpose of the patent system, and contradicts multiple sections of the MPEP (see, for example, MPEP 2164.02 regarding working examples). Such a standard would transform the USPTO into the FDA, and would undermine the role of the patent process in providing the sort of protection that rewards innovation and safeguards the rights of inventors.

“[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for ‘preferred’ materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.” *In re Goffe*, 542 F.2d 564, 567, 1991 USPQ 419, 431 (CCPA 1976)

However, Applicants' arguments do not rest solely upon the hope that the patent process will not ultimately undermine the very inventiveness it was designed to protect and reward. The specification provides extensive guidance to allow one of skill in the art to practice the claimed invention without undue experimentation. Applicants direct the Examiner's attention to the following exemplary passages from the specification: page 6, lines 19-35; page 7, lines 1-12; page 20, lines 1-34; page 25, lines 3-35; page 26, lines 1-29; Examples 1-2; and Examples 6-7. Applicants contend that the specification taken as a whole and as exemplified by these passages provide ample guidance to allow one of skill in the art to practice the claimed invention throughout its scope.

Applicants remind the Examiner that the criteria for satisfying the requirements under 35 U.S.C. 112, first paragraph, do not require that one of skill in the art can practice the claimed invention without any experimentation. All that is required is that the experimentation required to practice the invention not be undue. This sentiment is echoed by both the MPEP and the courts which have held that “[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance.” *In re Colianni*, 561 F.2d 220, 224, 195

USPQ 150, 153 (CCPA 1977). “The test is not merely quantitative, since a considerable amount of experimentation is permissible if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicants contend that the facts in the present case support the conclusion that the specification provides ample guidance to allow one of skill in the art to practice the claimed invention without undue experimentation.

Applicants remind the Examiner that there is no requirement in patent law that the claimed invention be supported with working examples in order to satisfy the statutory requirements of patentability. In accordance with MPEP 2164.02, “An example may be ‘working’ or ‘prophetic.’ A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.” This sentiment was supported by the courts in the findings of *Gould v Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987) and *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956). In *Gould*, the Federal Circuit found that “[t]he mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it.”

Applicants contend that the claims are enabled throughout their scope. The specification provides extensive guidance such that one of skill in the art can practice the claimed invention without undue experimentation. Applicants contend that the level of skill among those practicing on the art is very high, and that the specification provides extensive guidance to such highly skilled artisans. These factors, in combination with the instructions set forth in the MPEP, as well as the mandate of the courts which specify that an application need not enable one of skill in the art to practice the claimed invention without **any** experimentation, support the enablement of the claimed invention. All that is required is that one of skill in the art be enabled to practice the claimed invention without undue experimentation, and such is the case here.

Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out certain embodiments of Applicants’ invention. Applicants’ amendments are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Should the Examiner maintain the rejection in light of Applicants’ arguments and amendments, Applicants

respectfully request that the Examiner make of record the particular references upon which the Examiner is relying so that Applicants will have the opportunity to review those references and prepare an appropriate response. Reconsideration and withdrawal of this rejection are respectfully requested.

6. Claims 77-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

a. The Examiner alleges that recitation of cultures that are 50% or 60% pure is inconsistent with the definition of substantially pure provided in the specification, and thus claims reciting levels of purity of 50% or 60% are unclear. Applicants contend that one of skill in the art would readily appreciate the metes and bounds of the claimed subject matter in light of the limitations explicitly recited in the claims and in light of the specification. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out the claimed subject matter. Applicants' amendments are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are respectfully requested.

b. Claims 69, 71-77 and 81 are rejected for allegedly omitting essential elements from the claims. Applicants contend that the claims clearly delineate that which Applicants regard as the invention, and do not include any ambiguous language which would prevent one of skill in the art from readily appreciating the metes and bounds of the claimed subject matter. Accordingly, claims 69, 71-77 and 81 satisfy all of the requirements under 35 U.S.C. 112, second paragraph. If the Examiner doubts whether the application provides sufficient guidance to allow one of skill in the art to practice the claimed invention, then the Examiner should reject the claims under 35 U.S.C. 112, first paragraph, and allow Applicants the opportunity to refute such an allegation.

Despite Applicants' contention that the claims satisfy all of the requirements under 35 U.S.C. 112, second paragraph, Applicants have amended the claims to further specify the claimed subject matter. Applicants' amendments are not in acquiescence to the rejection, and

Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal of this rejection are requested.

7. Claims 55, 63-65, 69, 77 and 78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 8, 15, 25 and 26 of U.S. Patent No. 6,326,201. Applicants will submit a terminal disclaimer, if necessary, upon indication of subject matter that is allowable in all other respects.



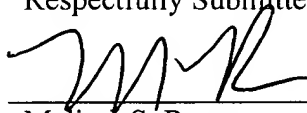
### CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

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Respectfully Submitted,



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